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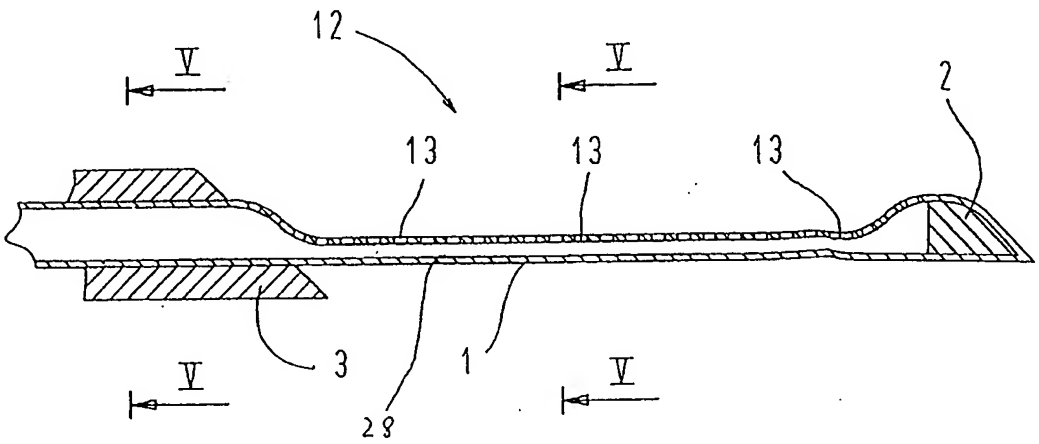
(54) Title: BIOPSY NEEDLE



(57) Abstract

A biopsy needle comprising piercing means (1) designed to penetrate into an organic tissue and provided with a housing (12) designed to receive a sample (23) of said organic tissue, and a hollow body (3) slidable on said piercing means (1) between a first position wherein said piercing means (1) protrudes from said hollow body (3) for such a distance as to allow said housing (12) to be positioned outside said hollow body (3) and a second position wherein said housing (12) is positioned inside the hollow body (3), an end of the hollow body (3) being made sharp, said piercing means (1) are provided with an inner cavity (28) communicating with said housing (12), vacuum means being provided to generate a vacuum in said cavity (28).

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BIOPSY NEEDLE

The invention concerns a biopsy needle, particularly a guillotine biopsy needle, that is a tool designed to take samples from organs or tissues of patients in order to diagnose the nature of a pathological process.

Biopsy needles of a type known as "guillotine needles" are known comprising a substantially cylindrical mandrel having an end near which a housing is provided- for instance a housing obtained by flattening a portion of the mandrel - designed to receive a sample to be taken, and an hollow needle with a sharp point, said needle being slidably coupled with the outer surface of the mandrel.

The housing has such dimensions as to receive a tissue sample having a size suitable for being used for histological tests.

In order to effect a biopsy, the tool is introduced into the body of a patient, keeping the mandrel drawn back in the hollow needle so that only the point of mandrel protrudes from the needle. When the point of the mandrel reaches the area of the patient body from which a sample is to be taken, the mandrel is driven out of the needle by sliding it with respect to the needle. In this way, a tissue portion surrounding the mandrel penetrates into the housing provided in the mandrel. Then, the housing is covered by the hollow needle so that the sharp point of the latter severs from the surrounding tissues, like a guillotine, said tissue portion penetrated into the housing.

When using the biopsy needle described above, there is no certainty that a suitable portion of tissue penetrates actually into the housing on the mandrel, when the needle is introduced into the body of a patient. Therefore, it often happens that, after the needle has been withdrawn, one realizes that no sample, or a sample having a size unsuitable for hystological tests, has been taken. In that event, it is necessary to repeat the biopsy, which involves further pain

and shock for the patient.

It is an object of the present invention to eliminate the drawbacks mentioned above, paticularly to provide a biopsy needle of the type mentioned above which makes sure that a tissue sample having a suitable size is taken from the body of the patient, thus preventing any chance of the biopsy being to be repeated.

The object of the invention is attained by providing a biopsy needle, comprising piercing means designed to penetrate into an organic tissue and provided with a housing designed to receive a sample of said tissue, and a hollow body slidable on said piercing means from a first position wherein said piercing means protrudes from said hollow body for such a distance as to allow said housing to be positioned outside said hollow body and a second position wherein said housing is positioned inside the hollow body, an end of the hollow body being made sharp, cahracterized in that said piercing means are provided with an inner cavity communicating with said housing, vacuum means being provided to generate a vacuum in said cavity.

The vacuum generated in said cavity is transmitted to the housing and makes a portion of tissue to be taken adhere to the housing, so that the presence of said portion in the housing is guaranteed, when the hollow body is slid on the piercing means to separate said portion from the surrounding tissue, on one hand, and the size of said portion is not substantially less than the size of the housing and is suitable for the tests that are to be made, on the other hand.

The present invention will be described now with reference to the four sheets of drawings here enclosed in which:

- figure 1 shows a longitudinal sectional view of a biopsy needle according to the invention, associated with a syringe;
- figure 2 shows an enlarged detail of figure 1;
- figure 3 shows the detail of figure 2 after a tissue sample

for biopsy has been taken;
- figure 4 shows a further enlarged detail of figure 1;
- figure 5 shows a cross section V-V of figure 2;
- figure 6 shows a cross section VI-VI of figure 2;
- figure 6a shows a section similar to that of figure 6, but concerning an alternative embodiment of the biopsy needle;
- figure 7 shows a section VII-VII of figure 2;
- figure 7a shows a section similar to that of figure 7, but concerning the alternative embodiment of figure 6a;
- figure 8 shows an alternative embodiment of the detail shown in figure 4;
- figure 9 shows a biopsy needle according to the invention, associated with a vacuum tube;
- figures 10 and 11 show a biopsy needle according to the invention associated with a syringe having an automatic return plunger.

Referring now to figures 1 and 2, a biopsy needle according to the invention comprises piercing mandrel means 1, ending at an end with a point 2 designed to facilitate penetration through the tissues of the body of a patient, and a needle hollow body 3 slidable on the mandrel 1, having a sharp end facing towards the point 2 of the mandrel 1.

The mandrel 1 is provided with an inner cavity 28 closed at an end by the point 2 and open at the opposite end.

An housing 12 is provided on the outer surface of the mandrel 1, near the point 2, said housing being designed to receive a sample 23 of tissue to be taken for biopsy and having such dimensions as to receive a tissue sample of a size suitable for being used for hystological tests.

Said housing 12 communicates with the inner cavity 28 through holes 13 distributed on the surface of the housing.

In a first embodiment, shown in figures 6 and 7, the mandrel 1, in its portion comprising the housing 12, exhibits a flattened, elongated cross section shaped as a kidney, the cavity 28 being correspondingly shaped.

In a second embodiment, shown in figures 6a and 7a, the mandrel

1, in its portion comprising the housing 12, exhibits a cross section substantially shaped as a sector of a circle, the cavity 28 being correspondingly shaped. The bottom of the hosing 12 is shaped as a pair of slopes in order to increase the contact surface between the tissue sample 23 and the bottom of the housing 12.

The hollow needle 3 is installed on a slide 4, slidable between a first and a second position on a guide 6 protruding from a support 7 parallely to the hollow needle 3. The mandrel 1 passes through both the slide 4 and the support 7, with a sealing gasket 14 interposed between the slide 4 and the mandrel. The slide may be slid on the guide 6 by using an handling protrusion 5 provided on the slide.

When the slide 4 is in said first position, the mandrel 1 protrudes from the hollow needle 3 for such a distance as to allow the housing 12 to be positioned completely outside the hollow needle 3.

On the contrary, when the slide 4 is in said second position, the housing 12 is positioned completely inside the hollow needle 3.

The end of the mandrel 1 opposite to the point 2 may be inserted into the cone end of a conventional syringe 11, so that tha cavity 28 of the mandrel 1 communicates with the interior of the syringe. The syringe 11 is provided with a handle 10 and a plunger 9, an end of which has an handling disc 9a. The plunger 9 is substantially sealingly slidable at the inside of the syringe between a forward position, wherein the plunger is positioned near a bottom end 30 of the syringe, or in contact with it, and a second position, wherein the plunger is distanced away from said bottom end 30.

Figure 8 shows an alternative embodiment of the invention, wherein the displacement of the slide 4 from said first position to said second position is automatically obtainable.

For this purpose, the end of the slide 4 facing towards the support 7 is provided with a housing in which first elastic

means, such as a spring 18, is housed, said spring being compressed between the slide and the support 7, when the slide 4 is in said first position.

In order to keep the slide 4 in said first position, against the action of the spring 18, the slide is provided with first stop means comprising a protrusion 17 with may be engaged with a pawl 16 provided on the support 7. The pawl 16 is associated with elastic handling means 16a designed to allow the disengagement of the protrusion 17 in order to free the spring 18 so that it can automatically push the slide 4 towards said second position.

The guide 6 is provided, at its end facing towards the point 2 of the mandrel 1, with further stop means 20 for the slide 4 cooperating with a corresponding protrusion 19 of the slide to stop the slide in said second position.

Figure 9 shows a further embodiment of the present invention, wherein the end 24 of the mandrel 1 opposite to the point 2 is inserted in a cylinder 21 inside which a vacuum tube 22 is sealingly slidable, said vacuum tube having an end facing towards the mandrel 1 provided with a diaphragm 22a which may be pierced. The end 24 of the mandrel 1 is so shaped as to be able to pierce the diaphragm 22a, when the diaphragm if pushed against said end by sliding the vacuum tube at the inside of the cylinder 21. When the diaphragm 22a is pierced, the cavity 28 of the mandrel 1 is put in communication with the vacuum tube 22 and vacuum is created at the inside of the cavity.

Figures 10 and 11 show a still further embodiment of the invention, wherein the displacement of the plunger 9 of the syringe 11 between said forward position and said backward poition is obtained automatically.

For this purpose, the syringe 11, at its end opposite to the cone end 8, is provided with an annular projection 31 against which a first end of second elastic means, such as a spring 25, rests, the spring 25 being wound on the piston 9 and having a second end resting against the handling disc 9a of the plunger 9.

When the plunger 9 is in said forward position, the spring 25 is compressed between the annular projection 31 and the handling disc 9a.

In order to keep the plunger 9 in said forward position, against the action of the spring 25, second stop means is provided comprising a pair of elastic straps 26 extending backward from said annular projection 31 and located at opposite sides thereof.

Said straps 26 are provided with protrusions 27 facing each other designed to engage the elastic edge of the handling disc 9a, in order to lock the plunger in said forward position.

The straps 26 are connected to a handling cross-piece 29.

If the handling cross-piece is pushed towards the plunger 9, the straps 26 deform elastically bending towards the outside of the plunger 9 and the protrusions 27 disengage from the handling disc 9a allowing the spring 25 to push the plunger 9 towards said backward position. The cross-piece 29 acts also as stop means for the plunger 9, when the plunger reaches said backward position.

Use of the needle according to the invention, referring to the embodiment shown in figures 1 to 7, is as follows: the plunger 9 is pushed towards said forward position, acting on the handling disc 9a, and the slide 4 is slid in said second position, acting on the handling protrusion 5, so that only the point 2 of the mandrel 1 protrudes from the hollow needle 3. Then, the biopsy needle is introduced into the body of the patient untill the point 2 of the mandrel 1 reaches a position near the area from which a tissue sample is to be taken for biopsy. Now, the slide 4 is moved to said first position so that the mandrel 1 comes out of the hollow needle 3 untill the housing 12 is positioned completely outside the needle.

The mandrel 1 is then further introduced into the body of the patient untill the housing 12 is positioned in the area from which the tissue sample for biopsy is to be taken, and the plunger 9 of the syringe is moved from said forward position to said backward position, acting on the handling disc 9a: in

this way, a vacuum is created inside the syringe 11 and is transmitted to the cavity 28 of the mandrel 1 sucking up, through the holes 13 provided at the bottom of the housing 12, the tissue surrounding said housing, which adheres thus to the bottom of the housing 12.

The slide 4 is then moved from said first position to said second position, while the piston 9 is kept in said backward position, so that the hollow needle 3 covers completely the housing 12 and severs from the surrounding tissue, by means of its sharp end acting as a guillotine, the portion of tissue adhering to the bottom of the housing 3, said portion being thus trapped at the inside of the hollow needle 3.

The biopsy needle may now be withdrawn from the body of the patient and one can be sure both that the tissue sample for biopsy is positioned at the inside of the needle and can not fall out of it, as the needle is withdrawn, and that the housing 12 is completely filled by the tissue sample, which has thus dimensions suitable for the tests that are to be performed.

In the embodiment of the invention shown in figures 6a and 7a, the shape of the bottom of the housing 12 featuring a pair of slopes makes available a wider contact surface between the tissue sample and said bottom, thus improving the adhesion effect between said sample and said bottom obtained by mens of the vacuum generated at the inside of the cavity 28.

In the embodiment shown in figure 8, the displacement of the slide 4 from said first position to said second position is achieved automatically by means of the action of the spring 18, acting on the handling means 16a to disengage the pawl 16 from the protrusion 17 of the slide 4.

This allows the slide 4 to be handled more easily and the severing of the tissue sample from the surrounding tissue to be obtained more rapidly, due to the thrust exerted by the spring 18 on the slide 4.

In the embodiment shown in figure 9, the vacuum at the inside of the cavity 28 of the mandrel 1 is obtained by connecting

said cavity with a tube 22 inside which vacuum has been created. This is obtained by sliding the tube 22 at the inside of the cylinder 21 until the diaphragm 22a is pressed against the piercing end 24 of the mandrel 1, thus causing piercing of the diaphragm 22a.

This embodiment of the invention makes possible to create, in a more easy, rapid and effective way, a vacuum at the inside of the cavity 28 of the mandrel, because the tube, when the diaphragm has been peforated, keeps its position, whilst, in the embodiment previosly described, the operator must keep the plunger 9 of the syringe 11 in its backward position, until the tissue sample is trapped at the inside of the hollow needle 3: all that because the vacuum generated at the inside of the syringe 11 by the displacement of the plunger 9 tends to draw the plunger towards its forward position.

In the embodiment of the invention shown in figures 10 and 11, the displacement of the plunger 9 from said forward position to said backward position to generate a vacuum at the inside of the syringe 11 is obtained automatically by means of the spring 25, which is compressed as the plunger is displaced towards its forward position. In order to cause the plunger to be displaced from said forward position to said backward position, it is enough to exert a thrust on the cross-piece 29, deforming the straps 26 until the projections 27 are disengaged from the edge of the handling disc 9a, thus allowing the spring 25 to push the plunger 9 towards its backward position, until the handling disc gets in contact with the cross-piece 29, which stops the displacement of the plunger.

The spring 25 prevents the vacuum generated at the inside of the syringe 11 by the displacement of the plunger from drawing the plunger towards its forward position.

In practice, the shape, materials, dimensions and excution details may be different from, but technically equivalent to, those described.

CLAIMS

1. A biopsy needle comprising piercing means (1) designed to penetrate into an organic tissue and provided with a housing (12) designed to receive a sample (23) of said organic tissue, and a hollow body (3) slidable on said piercing means (1) between a first position wherein said piercing means (1) protrudes from said hollow body (3) for such a distance as to allow said housing (12) to be positioned outside said hollow body (3) and a second position wherein said housing (12) is positioned inside the hollow body (3), an end of the hollow body (3) being made sharp, characterized in that said piercing means (1) are provided with an inner cavity (28) communicating with said housing (12), vacuum means being provided to generate a vacuum in said cavity (28).

2. A biopsy needle according to claim 1, wherein said cavity (28) communicates with said housing (12) through apertures (13) distributed on the surface of the housing (12).

3. A biopsy needle according to claim 1, or 2, wherein said cavity (28) is closed at a first end of said piercing means (1) and is open at a second end of said piercing means (1) opposite to said first end.

4. A biopsy needle according to any of preceding claims, wherein said piercing means (1) in its portion comprising said housing (12) exhibits a flattened, elongated cross section, the cavity (28) being correspondingly shaped.

5. A biopsy needle according any of claims 1 to 3, wherein said piercing means (1) in its portion comprising said housing (12) exhibits a cross section shaped substantially as a sector of a circle, the cavity (28) being correspondingly shaped.

6. A biopsy needle according to claim 5, wherein said

housing (12) has a bottom portion shaped as a pair of slopes.

7. A biopsy needle according to any of the preceding claims, wherein said vacuum means comprises a syringe (11) provided with a plunger (9) sealingly slidable inside the syringe from a forward position and a backward position.

8. A biopsy needle according to claim 7, wherein said piercing means (1) are inserted on said syringe (11) so that the interior of the syringe (11) communicates with said cavity (28).

9. A biopsy needle according to any of claims 1 to 6, wherein said vacuum means comprises a vacuum tube (22) slidable inside a tubular body (21).

10. A biopsy needle according to claim 9, wherein said vacuum tube (22) is provided at one end with a diaphragm (22a) which may be pierced.

11. A biopsy needle according to claim 11, wherein said piercing means (1) are coupled with said tubular body (21) so that its end (24) facing towards the vacuum tube (22) protrudes inside the tubular body (21), said end (24) being designed to pierce said diaphragm (22a).

12. A biopsy needle according to any of the preceding claims, wherein the hollow body (3) is associated with first elastic means (18) designed to displace it between said first position and said second position.

13. A biopsy needle according to claim 12, wherein said hollow body (3) cooperates with first stop means (16, 17) designed to keep it in said first position against the action of said elastic means (15).

14. A biopsy needle according to claim 7, wherein said plunger (9) cooperates with second elastic means (25) designed to displace it between said forward position and said backward position.

15. A biopsy needle according to claim 13, wherein the plunger (9) of the syringe (11) cooperates with second stop means (26, 27) designed to keep it in said forward position against the action of said elastic means (25).

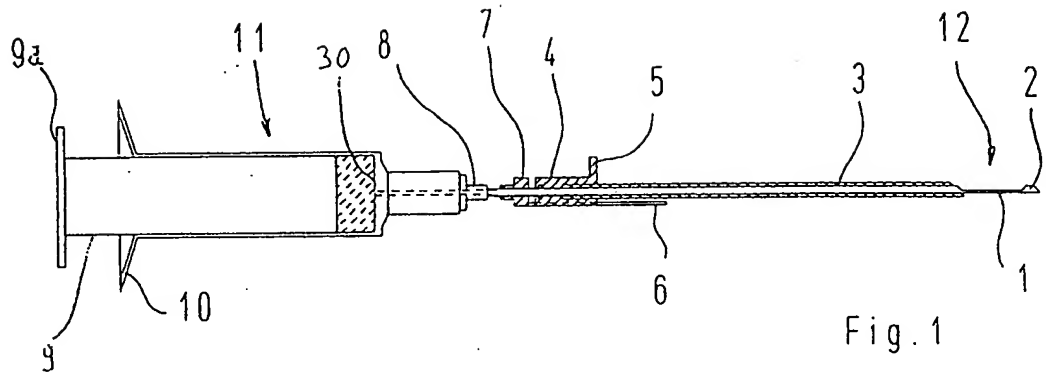


Fig.1

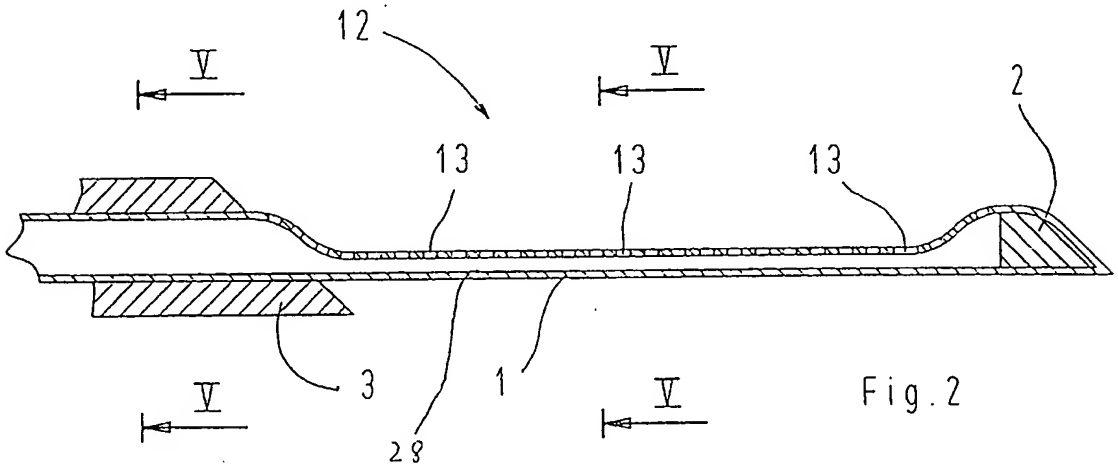


Fig.2

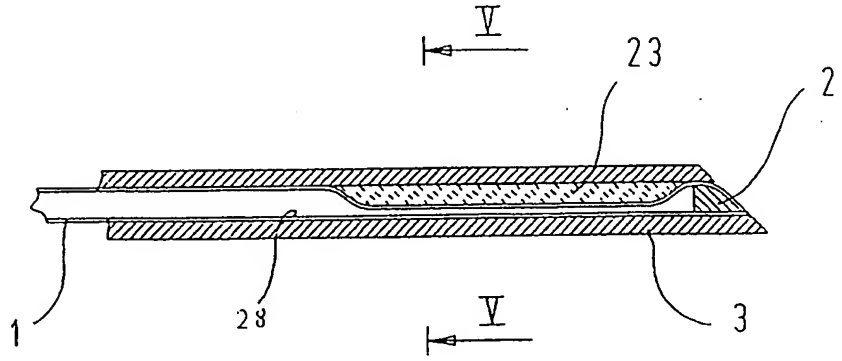


Fig.3

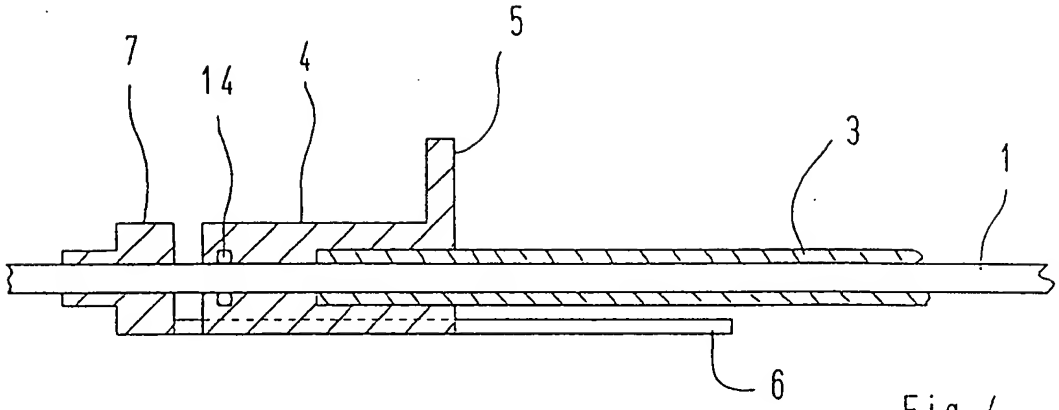


Fig.4

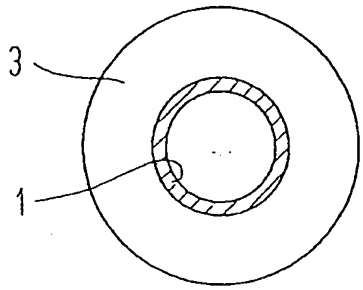


Fig.5

Fig.6

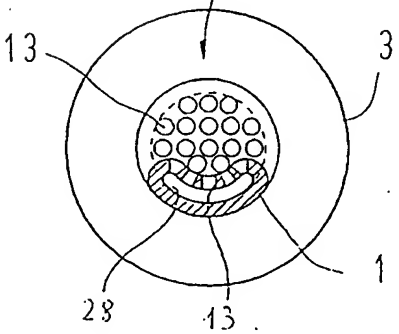


Fig.7

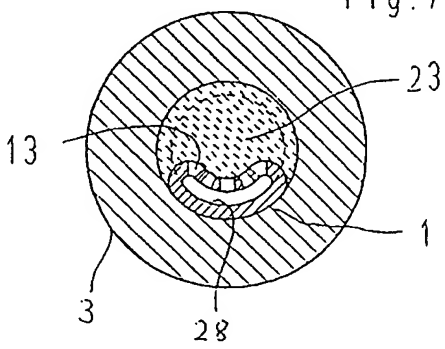


Fig.6a

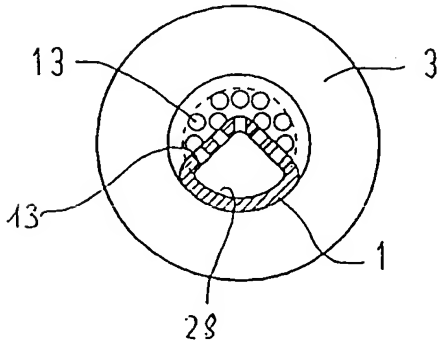
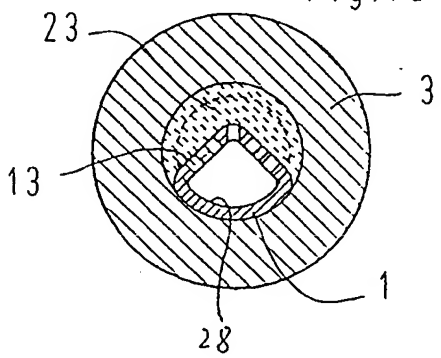


Fig.7a



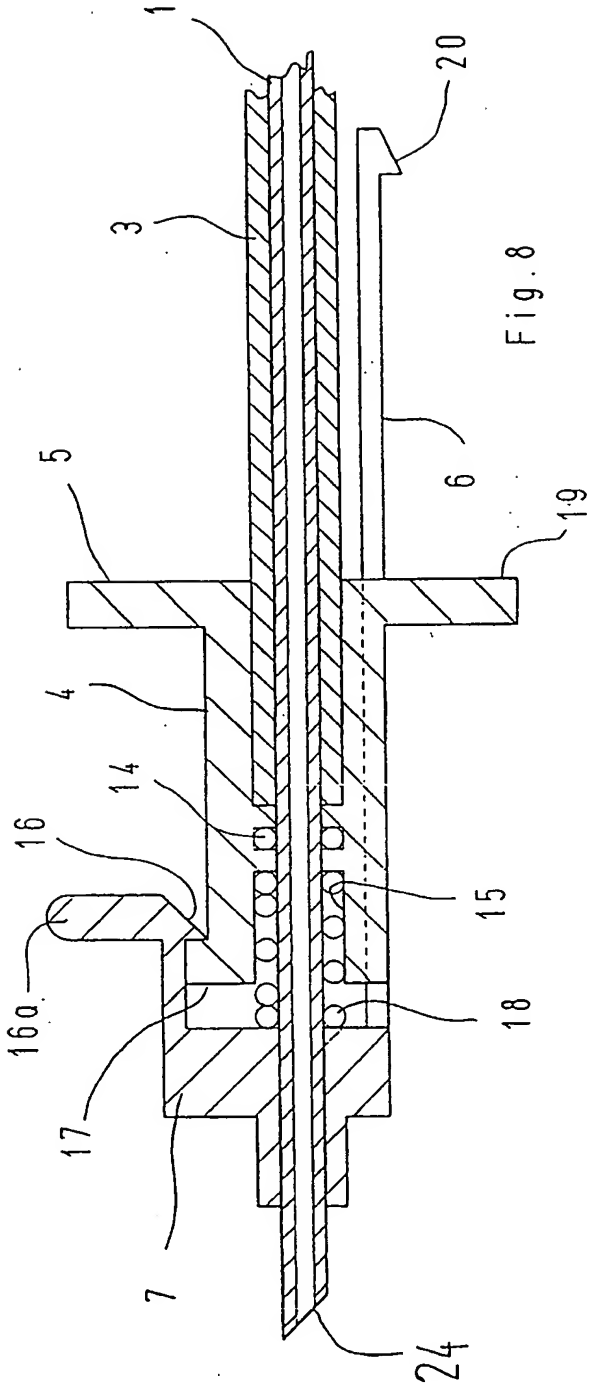

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Fig.8

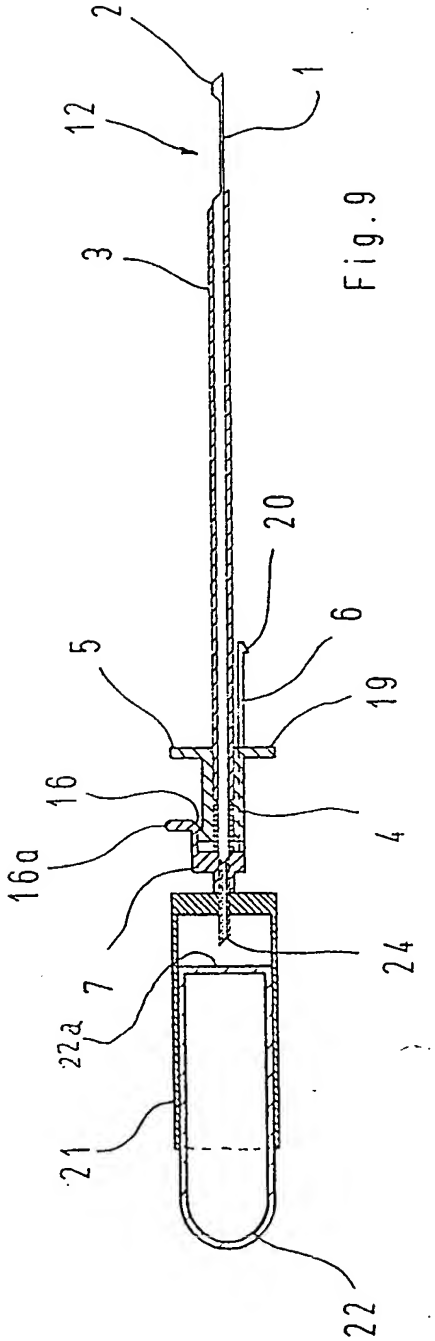
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Fig.9

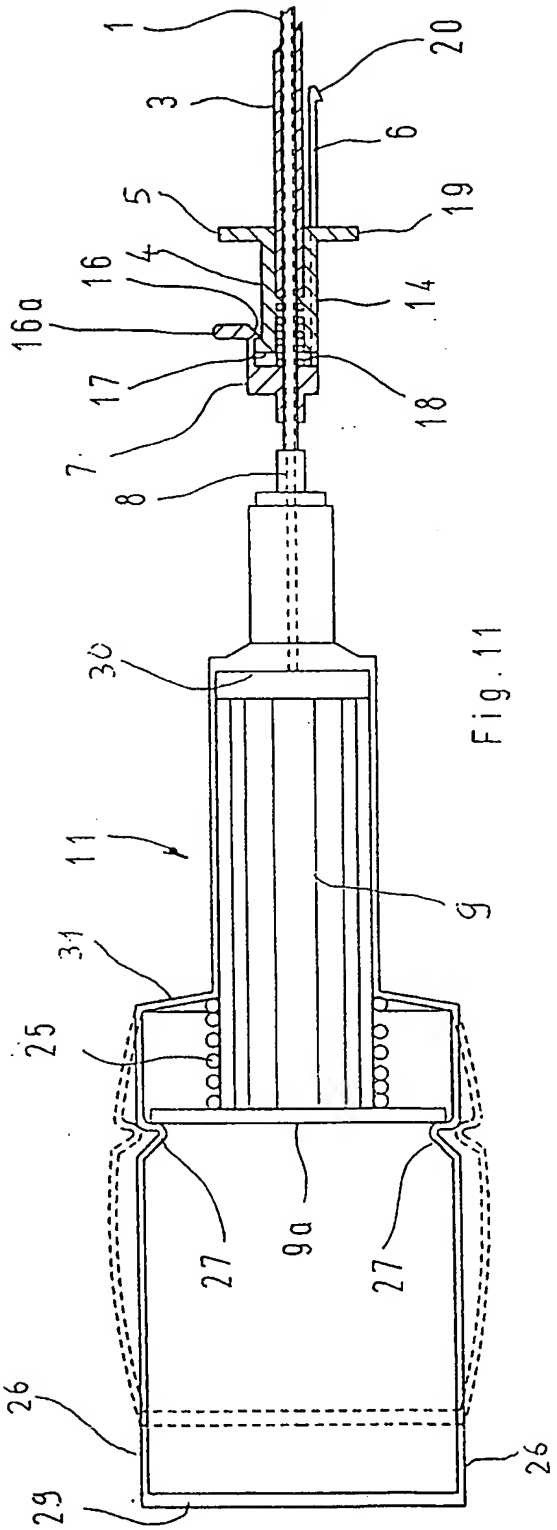
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Fig. 11

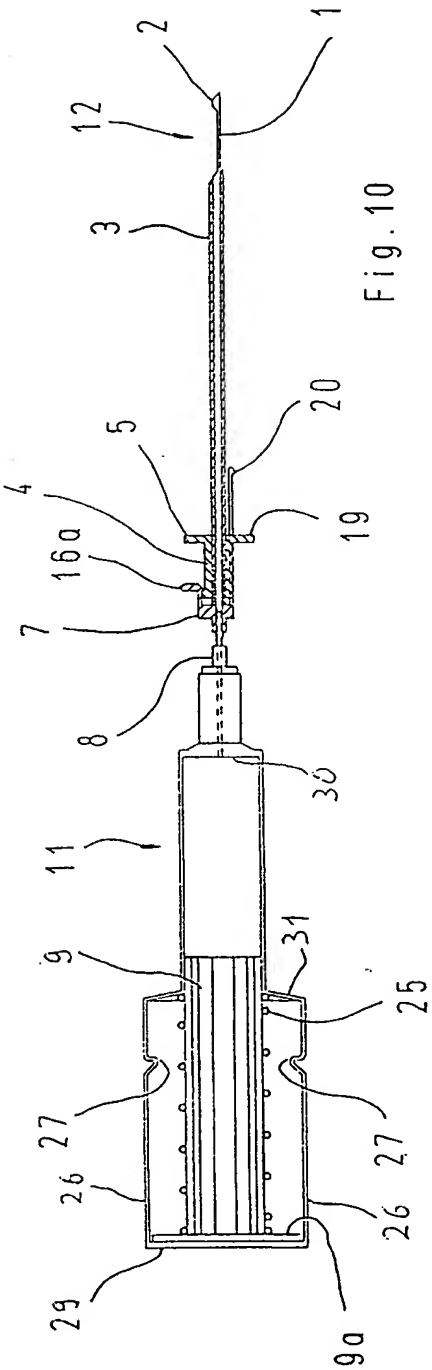
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Fig. 10

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/EP 97/06918

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B10/00

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 560 373 A (DE SANTIS STEPHEN A) 1 October 1996 see column 2, line 34 - line 57 see column 8, line 31 - line 38; figures 3,,12A,,13A	1,3-15
A	US 5 449 001 A (TERWILLIGER RICHARD A) 12 September 1995 see figure 3	6
A	WO 96 32147 A (ADVANCED CYTOMETRIX INC) 17 October 1996 see page 19, line 5 - line 9	9-11
A	WO 96 24289 A (BIOPSYS MEDICAL INC) 15 August 1996 see page 20, line 1 - line 11; figures 5-7	1,2

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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26 May 1998	04/06/1998

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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